REMARKS

Favorable reconsideration of this application in the light of the amendments and the following discussion is respectfully requested. Claims 1, 3 and 28 have been amended to more particularly define the invention. Support for the amendments to claims 1 and 28 can be found, for example, in the specification at page 10 lines 3-10 and page 12 lines 1-5. Support for the amendment to claim 3 can be found, for example, in the specification at page 7 lines 6-9. No new matter has been added.

Claims 13-27 and 31-53 have been canceled as directed to a non-elected invention. Claims 1-12 and 28-30 remain in the application for consideration.

Restriction Requirement

The Examiner required restriction under 35 USC §121 between Group I, claims 1-12 and 28-30, drawn to a method for reducing pain; and Group II, claims 13-27 and 31-53, drawn to an apparatus. The Examiner noted that inventions I and II are related as product and process of use, and thus can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the Examiner asserts that the product as claimed can be used as a materially different process such as band-aid.

It was concluded that because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

In addition, the Examiner has taken the position that the application contains claims directed to the following patentably distinct species of the claimed invention:

i/ figs. 1-3
ii/ fig. 4
iii/ figs. 5-7
iv/ fig. 8
v/ fig. 9
vi/ fig. 10
vii/ fig. 11
viii/ fig. 12
ix/ fig. 13-14

The Examiner has required an election under 35 U.S.C. 121 of a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, the Examiner states that no claims are generic.

During a telephone conversation with applicant's undersigned attorney on 09/22/03, a provisional election was made without traverse to prosecute the invention of group I, claims 1-12 and 28-30. Affirmation of this election has been required of applicant in replying to this Office Action. Claims 13-27, 31-53 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant hereby affirms the election to prosecute the invention of group I, claims 1-12 and 28-30. As noted, claims 13-27 and 31-53 have been canceled.

Applicant, however, respectfully traverses the election of species requirement. Applicant submits that the Examiner has not met the burden of proving the restriction of species is proper. MPEP§803 requires that two conditions be met for a proper requirement for restriction between patentably distinct inventions; i.e., (1) the inventions must be independent or distinct as claimed,

and (2) there must also be a serious burden on the Examiner if restriction is not required (See MPEP§803.02; §806.04(a)-(j); §808.01(a); and §808.02).

MPEP§803 also requires that the Examiner provide reasons to support the conclusion that the restriction of the various species is proper. The Office Action fails to provide any such reasons or examples to support the restriction requirements of the various species. Such reasons are hereby requested for each species that the Examiner believes should be restricted for the present invention. Applicant submits that in view of the preceding discussion, that without such reasons and examples, the restriction of the various species cannot be proper.

Moreover, applicant notes that at least claims 1-7, 9, 12 and 28-30 are generic, as each of the embodiments/species identified by the Examiner may be used in accordance with a method that falls within the scope of each of such claims.

Applicant hereby provisionally elects, with traverse as noted, Species viii, which the Examiner indicated is represented by Fig. 12 of the present application. Applicant submits that at least claims 1-12 and 28-30 read on the subject matter disclosed in Fig. 12.

Applicants have made the above election of species to comply with 35 U.S.C. 121 for the sole purpose of prosecution on the merits. Applicants' election should not be construed in any way to limit the scope or spirit of any of the embodiments of the present invention disclosed in the application.

Claim Rejections - 35 USC § 102

Claims 1-2, 7-10, 12 and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Kravitz (U.S. Patent No. 3,620,209).

The Office Action indicates that Kravitz teaches a method of reducing pain associated with skin penetration at a site with a needle comprising urging a skin-engaging surface (formed by 32 on the casing) of a pressure member (10) against the skin (12). The Examiner has taken the position that it is inherent that stimulation of the large diameter afferent sensory fibers and blocking of pain signal from the small diameter afferent pain nerve fibers in the skin proximate the site occurs since the device of Kravitz is similar in structure with the claimed device of applicant. The aperture is considered to be 14 where the needle / hypodermic syringe (16) is to be inserted. Further, Kravitz discloses that the pain normally associated with the injection at the area is reduced or minimal. (See abstract). Further, at col. 2, lines 43-49, Kravitz discloses that the stimulation of the pain center of the skin can be enhanced with the studs or projections (32), which extend outwardly from the casing (10). Kravitz further discloses that his device is for reducing pain of injection and to lessen the pain associated with such injections by pressing the device (case 10) against the skin.

Response to Claim Rejections - 35 USC § 102

Applicants respectfully traverse the rejection of claims 1-2, 7-10, 12 and 28-30 as being unpatentable over Kravitz. Kravitz is directed to a method of reducing the pain of injections that relies on vibrating a member against the skin of the patient to "stimulate the pain center of the skin" (column 2 lines 20-24). While Kravitz does not further discuss the mechanism by which it is alleged the method operates, it appears that by "pain center" Kravitz is referring to afferent nociceptors, or pain carrying nerves, primarily small diameter A-delta and C fibers. From the description in Kravitz, the intent is that the vibration of the device stimulates and then exhausts the pain receptors, thereby reducing pain perception.

Applicant has invented and has set forth in claim 1 a method for reducing the pain associated with penetration of the skin of a patient, comprising urging a skin engaging surface of a pressure member against the skin of a patient, to thereby depress the skin with sufficient force to stimulate the large diameter afferent sensory nerve fibers in the skin proximate the site and at least partially block pain signals from the small diameter afferent pain nerve fibers in the skin proximate the site. According to the Gate Control Theory of Pain, activation of the "pain gate" requires stimulation of large diameter afferent sensory neurons.

There are four types of large diameter sensory nerves: Meissner corpuscles (which respond primarily to light touch), Pacinian corpuscles (which respond primarily to deep pressure and are the most sensitive to vibration sense), Ruffini endings and Merkel discs. The first two, Meissner and Pacinian corpuscles, respond rapidly to touch and vibration, respectively. These two sensory receptors also have a rapid extinction rate; that is, they stop sending nerve impulses if the applied skin sensation continues for longer than a brief touch. Continuous stimulation as administered according to Kravitz (affixing a continuously vibrating mechanism to the skin surface by means of an armband) would not continue to stimulate these afferent sensory neurons due to the extinction effect, and they would cease responding after a short period of time. Only the Ruffini endings and Merkel discs, which primarily sense pressure, would respond to such continuous stimulation without demonstrating extinction of the nerve impulse.

As discussed, the method of Kravitz relies solely on vibrations at the surface of the skin. Kravitz does not teach or suggest urging a skin engaging surface of a pressure member against the skin of a patient proximate the site, to thereby depress the skin with sufficient force to stimulate the large diameter afferent sensory nerve fibers in the skin proximate the site and at least partially

block pain signals from the small diameter afferent pain nerve fibers in the skin proximate the site.

In this regard the Examiner alleges only that "it is inherent that stimulation of the large diameter afferent sensory fibers and blocking of pain signal from the small diameter afferent pain nerve fibers in the skin proximate the site occurs since the device of Kravitz is similar in structure with the claimed device of applicant" (emphasis supplied). However, applicant's claims currently under examination are directed to a method of achieving a reduction in the pain from injections and the like, rather than to a particular device, or even just to a particular effect.

While the device disclosed in Kravitz is similar *in some respects* to that disclosed in the present application, the respective methods of use are significantly different. Anticipation under 35 USC 102(b) requires the presence in a single prior art disclosure of all the elements of a claimed invention, arranged as in the claim (see *Connell v. Sears, Roebuck & Co.*, 220 USPQ 193, 198 (Fed. Cir. 1983)). As Kravitz fails to teach or suggest "urging a skin engaging surface of a pressure member against the skin of a patient proximate the site, to thereby depress the skin with sufficient force to stimulate the large diameter afferent sensory nerve fibers," Kravitz fails to disclose all of the elements of the claimed invention, arranged as in the claim.

Accordingly, the rejection of claim 1 as anticipated by Kravitz should be withdrawn. Claims 2, 7-10 and 12 all depend from claim 1 and are patentable over Kravitz at least on that basis. Furthermore, claim 28 also defines a method including "urging a skin engaging surface of a pressure member against the skin of the patient proximate the site, the skin engaging surface being comprised of a plurality of projections extending from the pressure member, to thereby depress the skin with sufficient force to stimulate the large diameter afferent sensory nerve fibers

in the skin." Thus, claim 28 (and claims 29 and 30, which depend therefrom) are patentable over Kravitz for the same reasons set forth with regard to claim 1.

Claim Rejections - 35 USC § 103

Claims 3-6 and 11 have rejected under 35 U.S.C. 103(a) as being unpatentable over Kravitz.

It is asserted that Kravitz discloses the claimed invention except for the material of the pressure member to be flexible, polymeric rigid or metal. As conceded by the Examiner, Kravitz is silent to the materials of the pressure member. However, the Examiner takes the position that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the materials of the pressure member to suit the area to which it would applied to, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious engineering choice.

With respect to claim 11, the Examiner acknowledges that Kravitz does not show a generally cloverleaf shape pressure member. Again, however, the Examiner takes the position that it would have been an obvious design choice to modify the horseshoe or u-shaped design of the Kravitz with a cloverleaf shape lacking any criticality of the shape. The Examiner is taking the position that matters relating to ornamentation only, which have no mechanical function, cannot be relied upon to patentably distinguish the claimed invention from the prior art. The particular shape of a product is of no patentable significance since it appears to be a matter of choice that a person of ordinary skill in the art would find obvious absent persuasive evidence that the particular configuration of the claimed container was significant.

Response to Claim Rejections - 35 USC § 103

Applicants respectfully traverse the rejection of claims 3-6 and 11 as unpatentable over Kravitz. These claims depend, either directly or indirectly, from claim 1 and are patentable at least on that basis.

Moreover, claim 3 further requires that the pressure member be "comprised of a material that is flexible enough to substantially conform to the contours of the skin in the vicinity of the site as the pressure member is urged against the skin." Kravitz lacks any suggestion for forming its casing of such a flexible material, and further lacks any suggestion for the desirability of using such a material. The mere allegation that the differences between the claimed subject matter and the prior art are obvious does not support a prima facie case of unpatentability. *In re Soli*, 137 USPQ 797 (CCPA 1963).

There is no motivation to be found in the art for modifying Kravitz as proposed by the Examiner. Kravitz relies on vibration, rather than use of the device to depress the skin with sufficient force to stimulate the large diameter afferent sensory nerve fibers, so that use of a flexible material would have no advantage in the method of Kravitz. In addition, the casing of Kravitz must house the vibratory means such as an electrically powered motor. Thus, the casing of Kravitz cannot be flexible enough to substantially conform to the contours of the skin, or damage would likely result to the housed motor. This is a strong disincentive to modify Kravitz as proposed in the Office Action.

Claim 11 also further defines over Kravitz, by requiring the perimeter of the pressure member to define a generally cloverleaf shape, a shape the Examiner admits is not suggested by Kravitz. Contrary to the Examiner's assertion, the shape defined by claim 11 is not merely

ornamental. As noted in the specification, for example at page 9 lines 14-17, such a shape facilitates handling of the pressure member, an advantage with the claimed method, where the pressure member is urged against and depresses the skin of the patient. On the other hand, there would be no motivation to modify Kravitz as proposed in the Office Action, as Kravitz provides arm straps 18 and 20 to hold the device in position.

For all of these reasons, a prima facie case of obviousness of the claims 3-6 and 11 based upon Kravitz has not been established. The rejections should therefore be withdrawn.

CONCLUSION

Favorable reconsideration of the present application and the passing of this case to issue with all claims allowed are courteously solicited. Should the Examiner wish to discuss any aspect of this application, applicants' attorney suggests a telephone interview in order to expedite the prosecution of the application.

Respectfully submitted,

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